UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,323	12/31/2003	Rey-Yuh Wu	03-1119	1770

20306 7590 01/05/2007

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,323	WU ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/02/2004; 6/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Stedman's Dictionary*.

Response to the Amendment

The Amendment filed on 10/06/2006 in response to the previous Non-Final Office Action (02/28/2006) is acknowledged and has been entered.

Claims 1-6 and 13 are currently pending and under consideration.

The Declaration under 37 CFR 1.132 filed on 6/26/2006 is insufficient to overcome the rejection of claims 1 and 3-6 under 35 U.S.C. 102(b) based upon Kexin et al. (Chinese Journal of Combined Traditional and Modern Medicine 1999; 19: 11-13, translated) as set forth in the last Office action because: the Declaration does not appear to clearly set forth that the composition referred to as Shenqi Fuzheng as described by Kexin et al. does not inhibit carcinogenesis and metastasis, and therefore, is not the same as claimed. The instant Declaration provides experiments comparing the composition of Kexin et al. against the claimed composition which reports that the compositions behaved differently. For example, the Declaration teaches that Shenqi Fuzeng (with a dosage of 10 mL/kg) failed to inhibit colon carcinogenesis and metastasis significantly (Appendix 1). On the other hand, the Declaration teaches that 0.6 g/kg of the Astagalus radix and Codonopsis pilosulae radix mixed extracts inhibited colon carcinogenesis and metastasis significantly. Thus, while the Examiner agrees that the Declaration clearly sets forth that 0.6 g/kg or 0.2 g/kg of the Astagalus radix and Codonopsis pilosulae radix mixed extracts inhibited colon carcinogenesis and metastasis more significantly than the composition referred to as Shenqi Fuzheng as described by Kexin et al., the Examiner recognizes that claim 1 does not recite a specific dose and does not require a more significant inhibition activity. In other words, Figure 1 of the Declaration only shows that the Astagalus radix and Codonopsis pilosulae radix mixed extracts inhibited colon carcinogenesis and metastasis more significantly than the composition referred to as Shenqi Fuzheng as described by Kexin et al., but does not show that Shenqi Fuzheng does not work.

Information Disclosure Statement

The Information Disclosure Statement filed on 6/26/2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

The Zang et al. reference previously submitted in the March 30, 2004 IDS and the Statement of Relevancy of the Zang et al. reference accompanying the March 30, 2004 IDS is acknowledged and has been considered. As such, the submission is in compliance with the provisions of 37 CFR 1.97.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-6 **remain** rejected under 35 U.S.C. 102(b) as being anticipated by Kexin et al. (Chinese Journal of Combined Traditional and Modern Medicine 1999; 19: 11-13, translated).

Kexin et al. teach the clinical effects of Shenqi Fuzheng in treating gastric cancer (abstract). With regards to Shenqi Fuzheng, the reference teaches that Shenqi Fuzheng consists of Huang Qi (astragalus root) and Dang Shen (pilose asiabell root) (page 2 of translation, *Treatment Method*) and is produced as a solution for injection. Thus, while Kexin et al. do not explicitly teach that *Codonopsis piola* and the species thereof is also referred to DangShen, it does not appear that the claim language

or limitation results in a manipulative difference as compared to the prior art disclosure because the specification discloses (page 1, lines 11-13 and page 4, lines 3-5) that *Codonopsis pilosulae* is also known as Dangshen which is the dried root of *Codonopsis pilola* (Franch.) Nannf, *Codonopsis tangshen* Oliv.. or *Codonopsis pilola* (Franch.) var. modesta (Nannf.) L.T. Moreover, although Kexin et al. do not explicitly teach that *Astragalus radix* and species thereof is also referred to Huang Qi, it does not appear that the claim language or limitation results in a manipulative difference as compared to the prior art disclosure because the specification discloses (page 1, lines 10-11 and 17-20) that *Astragalus radix* is also known as Huang Qi which is the dried root of *Astragalus mogholicus or Astragalus membranaceus*. Lastly, although Kexin et al. do not specifically teach that Shenqi Fuzheng can be used for the treatment of colon cancer, lung carcinoma or mammary carcinoma, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

In response to this rejection, Applicants assert that one of applicants tested the composition of Kexin et al. against the claimed composition and determined that the composition behave differently. Specifically, Applicants submit that the attached declaration which describes the testing and results, establishes that the claimed composition is not the same as the Kexin et al. composition. For example, Applicants submit that the Astragalus radix and Codonopsis pilosulae radix mixed extract prepared according to the subject invention has a significant effect on inhibiting carcinogenesis and metastasis. In contrast, Applicants assert that Shenqi Fuzheng described by Kexin et al. fails to show a significant effect on inhibiting carcinogenesis and metastasis. Thus, Applicants assert that the rejection of claims 1 and 3-6 be withdrawn.

These arguments have been carefully considered, but are not found persuasive.

In response to Applicants assertion that the compositions behave differently as set forth by the Declaration, the Examiner agrees that the Declaration clearly sets forth that 0.6 g/kg or 0.2 g/kg of the Astagalus radix and Codonopsis pilosulae radix mixed extracts inhibited colon carcinogenesis and metastasis more significantly than the composition referred to as Shenqi Fuzheng as described by Kexin et al.. However, the Examiner recognizes that the claim 1 does not specifically recite a specific dose and does not require a more significant inhibition activity. In other words, as noted

above, Figure 1 of the Declaration only shows that the *Astagalus radix* and *Codonopsis pilosulae* radix mixed extracts inhibited colon carcinogenesis and metastasis more significantly than the composition referred to as Shenqi Fuzheng as described by Kexin et al., but does not show that Shenqi Fuzheng does not work. As such, claims 1 and 3-6 **remain** rejected under 35 U.S.C. 102(b) as being anticipated by Kexin et al. (Chinese Journal of Combined Traditional and Modern Medicine 1999; 19: 11-13, translated).

Claims 1-6 **remain** rejected and **new** claim 13 is under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 2004/0105902, 2004).

Chen et al. teach a composition for treating prostate cancer comprising a therapeutically effective amount of *Astragali radix* (referred to also as Huang Qi) and *Codonopsis pilosulae radix* (page 2, paragraph 0017). With regards to the composition, the publication teaches that the composition consists of weight ratio of 1:1 (page 4, 2nd column, Example 1). Chen et al. further teach that the composition may be in the form of a solution and/or tablet/capsule (page 3, 1st column, paragraph 0026). Although Chen et al. do not specifically teach that the purified *Astragali radix* and *Codonopsis pilosulae radix* are extracted from a particular species, the claims are drawn to a composition comprising the two specific extracts, e.g., *Astragali radix* and *Codonopsis pilosulae radix*. Thus, the claimed composition appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Along the same lines, while Chen et al. do not specifically teach that the composition can be used for the treatment of colon cancer, lung carcinoma or mammary carcinoma, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

(Note: Applicants cite Chen et al. as being US 2004/015902 which is different from the Chen et al. cited in the Non-Final Rejection (Chen et al. 2004/0105902))

In response to this rejection, Applicants contend that the portion of Chen et al. cited by the examiner does not disclose or suggest the claimed invention. Moreover, Applicants contend that nowhere does Chen et al. disclose or suggest the combination of the two ingredients covered by the inventors. Applicants further assert that the inventors, in the application examples, demonstrate that the combination provides a synergistic effect in comparison to administration of the individual compositions. Lastly, Applicants contend that Chen et al. does not disclose the ratio of the two active ingredients disclosed in claim 2.

These arguments have been carefully considered, but are not found persuasive.

In response to Applicants assertion that Chen et al. does not disclose or suggest the claimed invention, the Examiner acknowledges that Chen et al. (page 2, paragraph 17) disclose various ingredients within a composition. However, the Examiner recognizes that Chen et al. disclose, in particular, a composition comprising two specific extracts, e.g., *Astragali radix* and *Codonopsis pilosulae radix,* (see page 4, list under paragraph 0040). In the instant case, the claims recite a composition comprising a therapeutically effective amount of *Astragali radix* and *Codonopsis pilosulae radix.* As such, the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Thus, while Chen et al. do not explicitly teach a composition consisting of the two extracts, Chen et al.'s composition comprising the two extracts anticipates the instant claims. With respect to Applicants arguments pertaining to synergy, it is noted that the features upon which applicant relies (i.e., synergy) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding Applicants assertion that Chen et al. does not disclose the ratio of the two active ingredients disclosed in claim 2, the Examiner acknowledges that Chen et al. do not explicitly teach that the composition an *Astragali radix* and *Codonopsis pilosulae radix* mixed extract is in a weight ration of 3:1 to 1:3. However, the Examiner recognizes that the publication teaches the composition consists of 5.7 % *Astragali radix* by weight and 5.7 % *Codonopsis pilosulae radix* by weight that would equate to a weight ratio of 1:1 which falls within the range claimed in 2 and 13(page 4, 2nd column, Example 1).

As such, claims 1-6 **remain** rejected and **new** claim 13 is under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 2004/0105902, 2004). In the instant case, new Claim 13 recites a composition consisting essentially of a therapeutically effective amount of Astragalus radix and Codonopsis pilosulae radix mixed extract, wherein the weight ratio of Astragalus radix: Codonopsis pilosulae radix in the mixed extract is from 3:1 to 1:3. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." Accordingly, Chen et al.'s composition anticipates claim 13.

New Rejections Necessitated by Amendment and/or upon Reconsideration:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant case, Claims 1, 2 and 13 are drawn to a composition for inhibiting carcinogenesis and metastasis of colon cancer, lung carcinoma or mammary adenocarcinoma in a subject and further, recite an active site of administering a composition. Thus, it is unclear whether Applicants are attempting to claim a composition or a method. For prior art purposes, the claims will be interpreted as a composition claim, i.e. a product, as previously submitted and examined.

Claim 13 is further rejected under 35 U.S.C. 112, second paragraph, because it is unclear which elements are excluded from the transitional phrase "consisting essentially of" in claim 13. There is no clear definition provided in the specification for ingredients or steps that would materially affect the composition or the method. See *PPG*, 156 F.3d at 1355, 48 USPQ 2d at 1355 for example. Therefore, the "consisting essentially of" language in the claim is being interpreted as "comprising", see the MPEP § 2111.03.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

New claim 13 recites a composition for inhibiting carcinogenesis and metastasis of colon cancer, lung carcinoma or mammary adenocarcinoma in a subject, comprising administering a composition consisting essentially of a therapeutically effective amount of an Astragalus radix and Codonopsis pilosulae radix mixed extract, wherein the weight ratio of Astagalus radix:Codonopsis pilosulae radix in the mixed extract is from 3:1 to 1:3. However, there is no written support for excluding any elements from the claimed method in the disclosure. Applicant has also not pointed to any disclosure that teaches which elements would alter the basic and novel characteristics of the invention. Therefore, it remains unclear what is to be materially excluded that would alter the invention. There is no teaching in the specification that would differentiate what is considered to be materially altering to the skilled artisan. The Office is not requiring a list of specific materials that would have to be excluded from the claimed method, but a general teaching of properties that would effect the invention. It is applicant's burden to teach what would materially alter the characteristics of the claimed invention. See *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964) and *Ex Parte Hoffman*, 12 USPQ2d 1061, 1063-64. With this type of teaching, the skilled artisan would be able to readily discern what would be excluded from the "consisting essentially of" claim language. However, since there is no general teaching of this kind in the specification, the claim remains rejected because it introduces new matter into the disclosure.

Claims 1-6 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for inhibiting metastasis and/or inhibiting tumor growth, does not reasonably provide enablement for a composition for inhibiting carcinogenesis of colon cancer, lung carcinoma or mammary adenocarcinoma in a subject, comprising administering a composition comprising a therapeutically effective amount of an

Astragalus radix and Codonopsis pilosulae radix mixed extract. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the nature of the invention, (2) the relative skill of those in the art, (3) the breadth of the claims, (4) the amount or direction or guidance presented, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the state of the prior art, and (8) the predictability or unpredictability of the art.

Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406) Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination

of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

The nature of the invention

The claims are drawn to a composition for inhibiting carcinogenesis and metastasis of colon cancer, lung cancer, or mammary adenocarcinoma in a subject, comprising administering a composition comprising a therapeutically effective amount of an Astragalus radix and Codonopsis pilosulae radix mixed extract. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Level of skill in the art

The level of skill in the art is deemed to be high, generally that of a PhD or MD.

The breadth of the claims

Applicants broadly claim a composition for inhibiting carcinogenesis and metastasis of colon cancer, lung cancer, or mammary adenocarcinoma in a subject, comprising administering a composition comprising a therapeutically effective amount of an Astragalus radix and Codonopsis pilosulae radix mixed extract. Thus, in view of Stedman's definition of carcinogenesis as being the orgin or production, or development of cancer, the claims encompass inhibiting the development of cancer, e.g., preventing cancer.

Guidance in the specification and Working Examples

The specification teaches that the present invention mainly provides a composition for inhibiting carcinogenesis and metastases comprising administering a therapeutically effective amount of a Astragalus radix and Codonopsis pilosulae radix mixed extract. For example, the specification teaches the effects of different composition comprising a Astragalus radix and Codonopsis pilosulae radix mixed extract on treating metastasis (beginning on page 20, Example 7). Thus, while the specification provides several examples of treating metastasis and inhibition of tumor growth, the specification appears to be silent on a correlation between the claimed composition and inhibiting

carcinogenesis, e.g., preventing cancer. As such, if there is no correlation then the examples do not constitute working examples. While it is understood that the absence of working examples should never be the sole reason for rejecting a claims as being broader than an enabling disclosure, the criticality of working examples in an unpredictable art, such as the prevention of cancer, is required for practice of the claimed invention.

Quantity of experimentation

The quantity of experimentation in the areas of cancer therapy is extremely large given the unpredictability associated with treating cancer in general and the lack of correlation of in vitro findings to in vivo success, and the fact that no known cure or preventive regimen is currently available for cancer.

The unpredictability of the art and the state of the prior art

The state of the art at the time of filing was such that one of skill could recognize that composition comprising Astragalus radix and Codonopsis pilosulae radix mixed extracts have been used for the treatment of cancer. For example, Kexin et al. (of record) teach the clinical effects of Shenqi Fuzheng in treating gastric cancer (abstract). With regards to Shenqi Fuzheng, the reference teaches that Shenqi Fuzheng consists of Huang Qi (astragalus root) and Dang Shen (pilose asiabell root) (page 2 of translation, *Treatment Method*) and is produced as a solution for injection. Along the same lines, Chen et al. (of record) teach a composition for treating prostate cancer comprising a therapeutically effective amount of *Astragali radix* (referred to also as Huang Qi) and *Codonopsis pilosulae radix* (page 2, paragraph 0017). Thus, while these two prior art references are directed to treating various cancer, those of skill in the art recognize that the prevention of cancer is highly unpredictable. The majority of studies suggest that the essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in *advance* of clinical cancer and *link* those results with subsequent histological confirmation of the presence or absence of disease. Further, such studies require the appropriate experimental models for analyzing chemo- or immunoprevention. For example, Granziero *et al.* (Eur. J. Immunol. 1999, 29:1127-1138) teach that many models are not suitable for testing immunotherapeutic approaches intended to cure cancer. They suggest that the optimal model (prostate cancer, in their case) would have spontaneous

tumor development in its natural location (1st column, page 1128) wherein disease progression would closely resemble the progression of the particular type of cancer. Hence, depending on the type of model employed one could establish a reasonable link between antecedent drug and subsequent knowledge of the prevention of the disease. Further, reasonable guidance with respect to correlating agents that prevent cancer may depend upon quantitative analysis from defined populations that have been successfully pre-screened and are predisposed to particular types of cancer. This type of data might be derived from widespread genetic analysis, cancer clusters, or family histories. For example, Byers, T. (CA Journal, Vol. 49, No. 6, Nov/Dec. 1999) teaches that randomized controlled trials are commonly regarded as the definitive study for proving causality (1st col., p.358), and that in controlled trials the random assignment of subjects to the intervention eliminates the problems of dietary recalls and controls the effects of both known and unknown confounding factors. Further, Byers suggests that chemo-preventitive trials be designed "long-term" such that testing occurs over many years (2nd col., p. 359).

Conclusion

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as written.

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

Therefore, NO claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

BF

12/18/2006

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600